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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,512	08/01/2001	Mattias Luukkonen	PRI-0019 (ORT-1461)	6102

7590                    03/20/2003

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[REDACTED] EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	13

DATE MAILED: 03/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

<b>Application No.</b> 09/921,512  <b>Examiner</b> Carolyn L Smith	<b>Applicant(s)</b> LUUKKONEN ET AL.	
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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### **Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### **Disposition of Claims**

- 4) Claim(s) 1-24 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-24 are subject to restriction and/or election requirement.

### **Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

### **Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### **Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____<br>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)<br>6) <input type="checkbox"/> Other: _____ |
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**Detailed Action**

***Restriction/Election***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 10-11, drawn to a method for inhibiting replication of KSHV by inhibiting c-Kit signaling pathway, classified in class 514, subclass 1.
- II. Claims 3 and 14-15, drawn to a method for inhibiting replication of KSHV by inhibiting type I sigma receptor signaling pathway, classified in class 514, subclass 1.
- III. Claims 2 and 12-13, drawn to a method for treatment of Kaposi sarcoma by inhibiting c-Kit signaling pathway, classified in class 514, subclass 1.
- IV. Claims 4 and 16-17, drawn to a method for treatment of Kaposi sarcoma by inhibiting type I sigma receptor signaling pathway, classified in class 514, subclass 1.
- V. Claim 5, drawn to a gene expression profile specific for the lytic phase of KSHV replication, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized specie election is also required.
- VI. Claim 6, drawn to a gene expression profile specific for the latent phase of KSHV replication, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized specie election is also required.
- VII. Claim 7, drawn to a microarray, classified in classes 435 and 536, subclasses 287.2 and 24.3, respectively. If this Group is elected, then the below summarized specie election is also required.

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VIII. Claim 8, drawn to a method for diagnosing KSHV or the stage of KSHV replication, classified in class 435, subclass 6. If this Group is elected, then TWO of the below summarized specie elections are also required.

IX. Claim 9, drawn to a method for identifying modulators of KSHV replication, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized specie election is also required.

X. Claims 18-24, drawn to a method of doing business, classified in classes 702 and 435, subclasses 19 and 6, respectively.

**Specie Election Requirement for Groups V-IX:**

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Groups V-IX:

These Groups contain patentably distinct species, namely genes listed in Table 2. Therefore, if any of Groups V-IX is chosen, the selection of a single specific gene from Table 2 is requested to be used for the initial examination of this application.

Additional Specie Election Requirement for Group VIII:

Specie A: KSHV diagnosis

Specie B: stage of KSHV replication

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for the appropriate election requirements for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness of the gene species in Groups V-IX is because the species are directed to different chemical types featuring different structures and functions. The distinctness of diagnosis versus stage of replication (Group VIII) is because these are distinct analysis types. The separate chemical and entity types of these species are often separately characterized and published in literature, thus adding to the search burden if all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the above-mentioned species are distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-IX are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene expression profiles and microarrays of Groups V, VI, and VII may be utilized in distinct usages as needed in Group I in a method for inhibiting replication of KSHV (via c-Kit signaling pathway inhibition), in a method for inhibiting replication of KSHV (via type I sigma receptor signaling pathway) as in Group II, in a method for treatment of Kaposi sarcoma (via c-Kit signaling pathway inhibition) as in Group III, in a method for treatment of Kaposi sarcoma (via type I sigma receptor signaling pathway) as in Group IV, in a method for diagnosing KSHV or the stage of KSHV replication as in Group VIII, in a method for identifying modulators of KSHV replication as in Group IX, in a method of doing business as in Group X, or alternatively, in gene discovery. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different

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subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

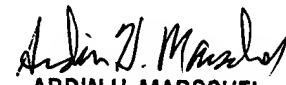
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 14, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER